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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/734,583

12/15/2003

Hidetoshi Andou

2923-595

2600

6449

7590

03/24/2009

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

1425 K STREET, N.W.

SUITE 800

WASHINGTON, DC 20005

EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1647

NOTIFICATION DATE

DELIVERY MODE

03/24/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/734,583 | <b>Applicant(s)</b><br>ANDOU ET AL. |  |
|                              | <b>Examiner</b><br>Marianne P. Allen | <b>Art Unit</b><br>1647             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 12-18 and 20 is/are pending in the application.
- 4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 16-18 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8, 12-18, 20 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/4/08 has been entered.

As indicated on the Advisory Action mailed 11/19/08, the After Final Amendment filed 11/4/08 has been entered. This amendment obviated the new matter rejection of claims 18-20.

### ***Election/Restrictions***

Claims 12-15 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/13/2006.

Claims 9-11 and 19 have been cancelled. Claims 1-8, 16-18, and 20 are under consideration by the examiner.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 16-18, and 20 are rejected under 35 U.S.C. 103(a) as being obvious over Andou et al. (U.S. Patent No. 6,551,801) in view of Hotten et al. (U.S. Patent No. 6,972,321).

This rejection is maintained for reasons of record. The presently claimed subject matter is not found in any of the parent applications except 10/414,954, filed 4/16/03. No other prior application teaches all limitations of the claims. As such, the effective filing date of the instant application is 4/16/03. Both Andou et al. and Hotten et al. are by other as the inventive entities are not identical to that of the instant application. They remain valid prior art against the instant claims.

The communication mailed 12/2/2008 provided the PTO assignment information for 10/743,583; U.S. Patent No. 6,972,321; and U.S. Patent No. 6,551,801. These documents do not establish common ownership now or at the time of the invention.

Applicant has now provided a statement concerning the common ownership of U.S. Patent No. 6,972,321 (Hotten et al.), U.S. Patent No. 6,551,801 (Andou et al.), and the instant application. It is reproduced below.

***STATEMENT OF COMMON OWNERSHIP***

*Applicants submit that the claimed invention and the two prior art references, U.S. Patent Nos. 6,972,321 to Hotten et al. and 6,551,801 to Andou et al. were owned by, or subject to an obligation of assignment, the same person, Mr. Michael Paulista, at the time the claimed invention was made. The common owner, Mr. Michael Paulista, was*

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*the sole owner of both HyGene AG and Biopharm Gesellschaft zur Biotechnologischen Entwicklung von Pharmaka GmbH at the time the claimed invention was made.*

This statement is not sufficient as it does not explicitly name the instant application by serial number. The application must be commonly owned with the prior art patents. This statement does not provide a clear and conspicuous statement of common ownership as discussed in MPEP 706.02(1)(2). This statement would only address the claims as presently written and not claims subsequently added or amended. It is noted that this statement was unaccompanied by any objective evidence that the two companies were solely owned by Mr. Michael Paulista at the time of the invention. As set forth in MPEP 706.02(1)(2), there is a material doubt as to the accuracy of applicant's representation of common ownership.

The prior art is not disqualified and the art rejection is maintained for reasons of record.

Claims 1-8, 16-18, and 20 are rejected under 35 U.S.C. 103(a) as being obvious over Andou et al. (WO 98/29559, published July 1998) in view of Hygene AG (EPO 1074620 A1, published February 2001).

The presently claimed subject matter is not found in any of the parent applications except 10/414,954, filed 4/16/03. No other prior application teaches all limitations of the claims. As such, the effective filing date of the instant application is 4/16/03. Both Andou et al. and HyGene AG al. are valid prior art against the instant claims under 35 USC 102(b). Applicant is advised that this prior art cannot be disqualified.

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Andou et al. is in the Japanese language. However, U.S. Patent No. 6,551,801 (as discussed above) is the national stage filing of the application PCT/JP97/04784 which published as WO 98/29559. As such, the disclosure would be identical to that of the '801 patent. Andou et al. discloses purification of monomeric BMP proteins including MP52 having all of the process limitations of the claims. See at least abstract and claims. Andou et al. does not teach mutating cysteine to prevent intermolecular disulfide bonds.

HyGene AG discloses producing monomeric BMP proteins including MP52 having a cysteine mutated to prevent intermolecular disulfide bonds. The protein can be produced recombinantly and be purified by any known means. See at least abstract, figures, paragraphs [20-22, 25-26, 33], and claims. HyGene AG does not teach the purification process limitations of the claims.

It would have been obvious to purify the mutated proteins of HyGene AG using the purification method of Andou et al. One would have been motivated to do so to simplify purification of a desirable protein. HyGene AG teaches the advantages of the mutated monomeric protein and Andou et al. teaches the advantages of the simplified purification steps. With mutation of the cysteines, the proteins would be incapable of dimerizing and thus the solution would be "free from oligomeric side products" as recited in claim 18.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/  
Primary Examiner, Art Unit 1647

mpa